IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.,	)	
	)	
Defendant.	)	
	)	

REPLY BRIEF TO MERCK & CO., INC.'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION IN LIGHT OF MERCK'S COVENANT NOT TO SUE

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INTRODUCTION

Plaintiff Merck & Co., Inc. ("Merck") submits this reply brief in support of its Motion to Dismiss. Merck seeks dismissal of this action with prejudice for lack of subject matter jurisdiction because the covenant not to sue that Merck has given to Apotex, Inc. ("Apotex") obviates any controversy between the parties. *Super Sack Mfg. Corp. v. Chase Packaging Corp.* 57 F.3d 1054 (Fed. Cir. 1995).

ARGUMENT

I. NO JURISDICTION EXISTS OVER APOTEX'S DECLARATORY JUDGMENT COUNTERCLAIM BECAUSE THERE IS NO CASE OR CONTROVERSY.

The Declaratory Judgment Act states that "any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration," provided there exists "a case of actual controversy within its jurisdiction." 28 U.S.C. § 2201(a). The statute requires a court to determine whether "there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of declaratory judgment." *Maryland Cas. Co. v. Pacific. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S. Ct. 510, 85 L. Ed. 826 (1941).

In determining whether such a controversy exists in patent cases seeking declaratory relief, the Federal Circuit has applied a two-part test: [1]

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[1] Apotex cites the fact that the Supreme Court has granted certiorari in *MedImmune, Inc. v. Genentech, Inc.* as support for its contention that a case or controversy exists in this case. 427 F.3d 958 (Fed. Cir. 2005), *cert granted*, 74 U.S.L.W. 3457 (U.S. Feb. 21, 2006) (No. 05-608). The issue in *MedImmune* is whether a patent licensee need breach its license agreement in order to establish an "actual controversy" in a declaratory action against the licensor. *Id.* In arguing against requiring a breach, the Solicitor General, in its amicus (continued . . .)

> There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993); *see also Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332 (Fed. Cir. 2005). "The element of threat or reasonable apprehension of suit turns on the conduct of the patentee, while the infringement element depends on the conduct of the asserted infringer." *BP Chems.*, 4 F.3d at 978. A party seeking a declaratory judgment bears the burden of establishing the existence of an actual controversy. *Sierra Applied Scis. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1373 (Fed. Cir. 2004). Moreover, the "actual controversy must be extant at all stages of review, not merely at the time the complaint is filed." *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975). Accordingly, the party seeking a declaratory judgment has the burden of establishing that "jurisdiction over its declaratory judgment action existed at, *and has continued since, the time the [counterclaim] was filed.*" *Super Sack*, 57 F.3d at 1058 (citation omitted) (emphasis added); *Sierra Applied Scis.*, 363 F.3d at 1373.

The Federal Circuit, therefore, has held that a patentee may divest a court of subject matter jurisdiction over an accused infringer's declaratory judgment action by covenanting not to sue the accused infringer for infringement. *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855-56 (Fed. Cir. 1999). Here, Merck has covenanted not to sue

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(. . . continued)

> brief, reasoned that "what matters instead is whether there is a genuine dispute between the parties that is sufficiently concrete, specific, and substantial to warrant judicial intervention." Brief for the United States as Amicus Curiae Supporting Petitioner at 21, *MedImmune, Inc v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005). Thus, the Solicitor General's brief supports Merck's position as the covenant not to sue has removed any genuine dispute between the parties, thus eliminating any case or controversy.

Apotex for infringement and, as a result, is asking this Court to dismiss this case with prejudice. Thus, because Apotex no longer has any reasonable apprehension of being sued by Merck, there is no controversy between the parties and thus, no subject matter jurisdiction. *See, e.g. Apotex Inc. v. Pfizer Inc.*, 2005 U.S. App. LEXIS 5930 (Fed. Cir. Apr. 11, 2005) (dismissing declaratory judgment action in an ANDA case because the patentee granted a covenant not to sue).[2]

II. THE COLLATERAL CONSEQUENCES DOCTRINE DOES NOT APPLY AND CANNOT SUPPORT THE COURT'S CONTINUED JURISDICTION OVER APOTEX'S DECLARATORY JUDGMENT COUNTERCLAIM.

Apotex wrongly argues that because of the Hatch-Waxman Act, there are "collateral consequences" that support continued jurisdiction, *i.e.*, that the case is not mooted by Merck's covenant not to sue and subsequent motion to dismiss with prejudice. Apotex Answering Brief at 9. Apotex claims that depriving it of a "triggering event"[3] that would allow it to enter the market at the same time as the first generic filer is a "collateral consequence" from a

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[2] The fact that Apotex would be prevented from going to market by the 180-day exclusivity period that Barr and Teva have as first ANDA filers does not create a case or controversy between Merck and Apotex. As the Federal Circuit noted in *Teva Pharms. USA Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1338 (Fed. Cir. 2005)(emphasis added):

> The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. *The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.*

[3] A triggering event is an event that initiates the 180-day exclusivity period for the first generic manufacturer to file an ANDA.

dismissal of this lawsuit that requires this Court to retain jurisdiction. *Id.* Apotex's argument misapplies the "collateral consequences" doctrine, which has no applicability here.

The notion of "collateral consequences" is a narrowly applied exception to mootness that is generally confined to criminal cases. "This situation arises, for example, in criminal cases in which the release of a prisoner would otherwise moot challenges to the propriety or legality of the conviction. Once a prisoner's sentence has expired, the prisoner must show some concrete and continuing injury other than the now-ended incarceration, that is some 'collateral consequence' of the conviction, if the suit [e.g. *habeas corpus* action] is to be maintained." 15 MOORE'S FEDERAL PRACTICE, § 101.99[3].

Apotex nonetheless characterizes the collateral consequences doctrine in broad and vague strokes, pointing to *Spencer v. Kemna*, 523 U.S. 1 (1998), for support. Apotex Answering Brief at 10. *Spencer*, however, was a *habeus corpus* proceeding in which the petitioner challenged his parole revocation. The United States Supreme Court held that the proceeding was moot because petitioner had already been released from prison and that there was no jurisdiction to sustain the lawsuit. Consistent with the Court's prior decision in *Lane v. Williams*, 455 U.S. 624 (1982), the Court held that concrete "collateral consequences" attributable to the parole revocation would have to be proven in order for the petitioner's *habeas* petition to be maintained and that the petitioner had failed to prove such consequences. *Spencer*, 523 U.S. at 14.

Apotex does not attempt to square the facts of this case with the framework laid out by *Spencer*.[4] In fact, Apotex cannot prove "collateral consequences" within the meaning of *Spencer* because Apotex is in no different situation now, with Merck's covenant not to sue and a dismissal with prejudice, than it would have been in had Merck never sued Apotex at all for patent infringement. In other words, Apotex will suffer no different consequences now than it would have suffered in the absence of any infringement claims by Merck. Thus, Apotex's claimed collateral injury arises not because of Merck's lawsuit, but rather is a product of the statutory scheme under Hatch Waxman. This Court does not have jurisdiction to address that claim. *Cf. Teva. v. Pfizer*, 395 F.3d at 1338.

[4] Apotex's reference to Thompson is inapposite. *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003). In that case, which involved a claim against the FDA for, *inter alia*, improperly listing patents in the Orange Book, the Federal Circuit held that the action was not moot because there was alleged injury caused by the FDA that could be rectified by the FDA if plaintiff prevailed on the merits. In this case, however, Apotex effectively concedes that it has no continuing dispute with Merck over patent infringement. *See* Apotex Answering Brief at 9 ("If this were an ordinary patent infringement case, then Merck's covenant not to sue would likely moot this case.").

CONCLUSION

For all the reasons set forth above and in Merck's Motion to Dismiss, and just as this Court recently held in *Merck & Co., Inc. v. Watson Laboratories, Inc.*, 2006 WL 1537375 (D. Del. 2006), Merck's Motion to Dismiss should be granted.

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CERTIFICATE OF SERVICE

I hereby certify that on September 7, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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